Chapter 4
Managing quality using ISO 9000

ISO 9000 is a tool to help you achieve an objective. It must not, itself, become the objective.

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Introduction

A historical perspective

ISO 9000 is a symptom of practices that were around centuries before anyone coined the term quality management. It is in some respects a natural progression that will continue to evolve. One cannot be certain when the concepts that underpin ISO 9000 were first derived. The principles of inspection against standards have been around since the Egyptians built the Pyramids. There is some evidence to suggest that associations of traders and craftsmen called *collegia* existed in ancient Rome as a means of monopolizing trade and establishing trading practices. The *collegia* did survive in the Byzantine Empire and particularly in what is now Istanbul. The *Book of the Prefect*, a manual of government probably drawn up around the year 900, describes an elaborate guild organization whose primary function was the imposition of rigid controls, especially for financial and tax raising purposes on every craft and trade in the city.[1] As communities grew in size and formed towns, craftsmen or merchants formed guilds for mutual aid and protection and for the furtherance of their professional interests. By the 11th century in Europe, guilds performed a variety of important functions in the local economy among which were their monopoly of trade, the setting of standards for the quality of goods and the integrity of trading practices. So what we find from a historical perspective is that

- Standards are an ancient concept that have survived several millennia.
- A means of verifying compliance often follows the setting of standards.

- The formalizing of working practices is centuries old and seen as a means to consistently meet standards.
- Market regulation (relative to the standard of goods and services) has been around for centuries for the protection of both craftsmen and traders.

Formal quality systems did not appear until the early 1950s. Quality Control, as an element of quality management emerged as a function in industry after WWII and the principles were codified by J M Juran in his Quality Control Handbook of 1951. In 1959 the first national standard, Mil Std 9858 on quality program requirements was issued by the US Department of Defense. This standard formed the foundation of all quality system standards that followed. This progression is illustrated in Figure 4.1.

The general philosophy of ISO 9000

Since the dawn of civilization the survival of communities has depended on trade. As communities grow they become more dependent on others providing goods and services they are unable to provide from their own resources. Trade continues to this day on the strength of the customer-supplier relationship. The relationship survives through trust and confidence. A reputation for delivering a product or a service to an agreed specification, at an agreed price on an agreed date is hard to win and organizations will protect their reputation against external threat at all costs. But reputations are often damaged not by those outside but by those inside the organization. Broken promises, whatever the cause, harm reputation and promises are broken when an organization does not do what it committed itself to do. This can arise either because the organization accepted a commitment it did not have the capability to meet or it had the capability but failed to manage it effectively.

This is what the ISO 9000 family of standards is all about. It is a set of criteria that when applied correctly, will help organizations develop the capability to create and retain satisfied customers. It is not a product standard – there are no requirements for specific products or services – only criteria that apply to the

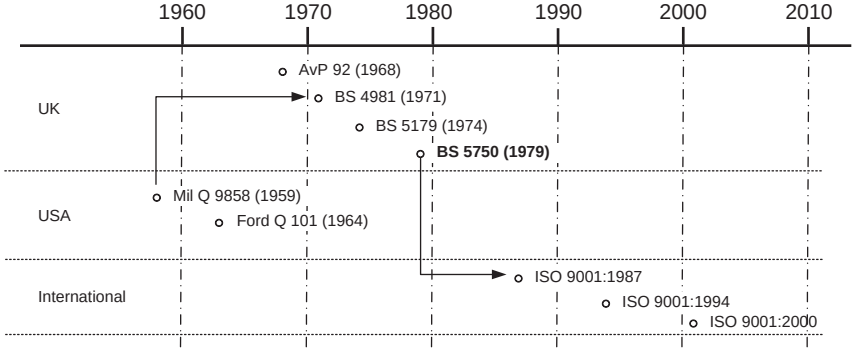

Figure 4.1 Evolution of ISO 9000

management of an organization when determining customer needs and expectations and supplying products and services that are intended to satisfy those needs and expectations.

Unfortunately, one cannot pick up one standard in the ISO 9000 family and get a clear understanding of what ISO 9000 is all about. Each standard was produced by a different committee and although ISO 9001 and ISO 9004 are supposed to be a consistent pair there are concepts within ISO 9000 that are not carried through clearly to the other standards and there are ambiguities that none of the standards resolve so one has to read between the lines, make connections and draw conclusions for it to make any sense. There follows an overview that aims to bridge this gap.

The *organization's purpose* is its reason for existing and can be expressed through vision and mission statements. The relationship between purpose, policy and objectives are blurred in the standard because from an assurance viewpoint *corporate values* seem to be irrelevant although with such revelations like Enron, Worldcom and Shell, it may not be long before values or corporate responsibility will be recognized by these standards.

The *quality policy* exists to shape behaviour and establishes the core values in an organization and therefore equates with the corporate policy – no benefits are gained from specifically expressing a quality policy and ignoring other policies because all policies influence the behaviours that are key to satisfying the needs of stakeholders.

Quality is a strategic objective that is established to fulfil the needs and expectations of all stakeholders and therefore equates with the corporate objectives – no benefits are gained from ranking quality equally with other objectives.

The *quality management system* is *the* management system that enables the organization to fulfil its purpose and mission. Organizations have only one system – no benefits are gained from formalizing part of a system that focuses on quality.

The *adequacy, suitability and effectiveness* of the management system is judged by how well the system enables the organization to achieve its objectives, operate efficiently and fulfil its purpose and mission – no benefits are gained from simply focusing on one aspect of performance when it is a combination of factors that deliver organizational performance.

A quest for confidence

In a nutshell

The ISO 9000 family of standards will stop you making promises you can't fulfil and help you keep those you can.

Customers need confidence that their suppliers can meet their quality, cost and delivery requirements and have a choice as to how they acquire this confidence. They can select their suppliers in one of several ways:

a) Purely on the basis of past performance, reputation or recommendation.

b) By assessing the capability of potential suppliers themselves.
c) On the basis of an assessment of capability performed by a third party.

Most customers select their suppliers using option (a) or (b) but there will be cases where these options are not appropriate either because there is no evidence for using option (a) or resources are not available to use option (b) or it is not economic. It is for these situations that a certification scheme was developed. Organizations submit to a third party audit that is performed by an accredited certification body independent of both customer and supplier. An audit is performed against the requirements of ISO 9001 and if no nonconformities are found, a certificate is awarded. This certificate provides evidence that the organization has the capability to meet customer and regulatory requirements relating to the supply of certain specified goods and services. Customers are now able to acquire the confidence they require simply by establishing whether a supplier holds an ISO 9001 certificate covering the type of products and services they are seeking. However, the credibility of the certificate rests on the competence of the auditor and the integrity of the certification body neither of which are guaranteed. (This is addressed further in Chapter 5.)

A quest for capability

Trading organizations need to create and retain satisfied customers to survive. This depends on their capability to:

a) Identify customer needs and expectations.
b) Convert customer needs and expectations into products and services that will satisfy them.
c) Attract customers to the organization.
d) Supply the products and services that meet customer requirements.

Many organizations develop their own ways of working and strive to satisfy their customers in the best way they know how. Increased global competition has led to more stringent customer expectations with regard to quality. To be competitive and to maintain good economic performance, organizations need to employ increasingly effective and efficient ways of managing the organization. In choosing the best way for them, they can either go through a process of trial and error, select from the vast body of knowledge on management, or utilize one or more management models available that combine proven principles and concepts. ISO 9000 represents one of these models. Others are Business Excellence Model, Six Sigma, Capability Maturity Model and Process Management.

Having given the organization the capability to do (a) to (d) above, customer confidence can be built up by reputation, customer assessments or third party assessment. If a customer requires confidence to be demonstrated through an ISO 9001 assessment, the organization has no option but to seek ISO 9001 certification if it wishes to retain business from that particular customer or market

In B2B relationships where confidence in capability is developed by reputation there might be no need for certification.

sector. In the UK alone there are about 2.5 million trading organizations and less than 2.5% have been registered to ISO 9001. It is therefore reasonable to assume that over 95% of organizations in the UK are able to give their customers confidence in their capability without becoming registered to ISO 9001 but this should not be assumed to mean that the concepts embodied in the ISO 9000 family of standards are flawed. It simply means that in the majority of organizations many of these concepts are employed but they have yet to find a need to pursue formal certification to ISO 9001. Nevertheless in the particular business-to-business relationship, confidence is developed by reputation rather than certification.

However, it is important to recognize that there is no requirement in ISO 9000 for certification. The family of standards can be used in helping an organization discover the right things to do as well as assess for itself the extent to which its goals and processes meet international standards. Only where customers are imposing ISO 9001 in purchase orders and contracts would it be necessary to obtain ISO 9001 certification.

Anatomy of the standards

There are three standards in the ISO 9000 family

ISO 9000 Quality management systems – Fundamentals and vocabulary

ISO 9001 Quality management systems – Requirements

ISO 9004 Quality management systems – Guidelines for performance improvements.

Each of the standards has a different purpose, intent, scope and applicability as indicated in Table 4.1.

These standards provide a vehicle for consolidating and communicating concepts in the field of quality management that have been approved by an international committee of representatives from national standards bodies. It is not their purpose to fuel the certification, consulting, training and publishing industries. The primary users of the standards are intended to be organizations acting as either customers or suppliers. But we should not forget that their primary purpose is to improve the capability of organizations to satisfy their customers and other stakeholders. Broken promises create massive problems for society thus making quality key to survival.

Basic approach

The most important clause in ISO 9000 is clause 2.3. There is a clause 2.3 in ISO 9000 but not in ISO 9001 and just because it is not in ISO 9001 doesn't mean you

Table 4.1 Overview of the ISO 9000 family of standards

Attribute	*ISO 9000 Family*	*ISO 9000*	*ISO 9001*	*ISO 9004*
Purpose	To assist organizations operate effective quality management systems	To facilitate common understanding of the concepts and language used in the family of standards	To provide an equitable basis for assessing the capability of organizations to meet customer and applicable regulatory requirements	To assist organizations satisfy the needs and expectations of all stakeholders
Intent	To facilitate mutual understanding in national and international trade and help organizations achieve sustained success	To be used in conjunction with ISO 9001 and ISO 9004	To be used for contractual and certification purposes	To assist organizations purpose continual improvement. It is not intended as a guide to meeting the requirements of ISO 9001
Scope	The management of quality	Defines the principles and fundamental concepts and terms used in the ISO 9000 family	Defines the requirements of a quality management system, the purpose of which is to enable organization to continually satisfy their customers	Provides guidelines for improving the performance of organizations and them to satisfy enabling all stakeholders
Applicability	Applies to all organizations regardless of size or complexity	Applies to all terms used in the ISO 9000 family	Applies where an organization needs to demonstrate its ability to provide products and services that meet customer and regulatory requirements and aims to enhance customer satisfaction	Applies to organizations seeking guidance on developing quality management systems and improving their performance
Facts and figures	3 Standards	81 Definitions	8 Sections 51 Clauses 250+ Requirements	8 Sections 64 Clauses No requirements

should ignore it. All three standards are equally important because they depend on each other. The principles, concepts and terminology that underpin ISO 9001 are addressed by ISO 9000 and those aspects that apply beyond product conformity are addressed by ISO 9004.

ISO 9000 clause 2.3 identifies the following basic steps to developing and implementing a quality management system: as a means to satisfying the needs and expectations of customers and other interested parties

1. Determine the needs and expectations of customers and other interested parties.
2. Establish the quality policy and quality objectives of the organization (these would be derived from 1 above).
3. Determine the processes and responsibilities necessary to attain the quality objectives.
4. Determine and provide the resources necessary to attain the quality objectives.
5. Establish methods to measure the effectiveness and efficiency of each process.
6. Apply these measures to determine the effectiveness and efficiency of each process.
7. Determine means of preventing nonconformities and eliminating their causes.
8. Establish and apply a process for continual improvement of the quality management system.

The four sections of ISO 9001 contain requirements that embody this approach but also prescribe requirements derived from the quality management principles that were addressed in Chapter 2. The requirements are not presented in any specific order or as a process and in some respects they follow no particular prescription except that they arise from failures that experience had shown led to poor product quality. The sections of ISO 9001 and ISO 9004 are as follows:

Introduction.
1. Scope.
2. Normative references.
3. Terms and definitions.
4. Quality management system.
5. Management responsibility.
6. Resource management.
7. Product realization.
8. Measurement, analysis and improvement.

Quality management system (development)

Section 4 of ISO 9001 contains the basic requirements for establishing a management system rather than any particular component of the system. In some instances they are duplicated in other Clauses of the standard but this is no bad

thing because it emphasizes the principle actions necessary to develop, implement, maintain and improve such a system. Unlike previous versions, the focus has moved away from documentation towards processes and therefore these general requirements capture some of the key activities that are required to develop an effective system.

Quality management system

4.1	General requirements
4.2	General documentation requirements
4.2.1	System documentation
4.2.2	Quality manual
4.2.3	Control of documents
4.2.4	Control of quality records

Although the Clauses in Section 4 are not intended as a sequence there is a relationship that can be represented as a cycle, but first we have to lift some Clauses from Section 5 to commence the cycle. The words in bold indicate the topics covered by the Clauses within Sections 4 and 5 of the standard. The cycle commences with the ***Organization's purpose*** (Clause 5.3 requires the quality policy has to be appropriate to the organization's purpose) through which are passed ***customer requirements*** (Clause 5.2 requires customer requirements to be determined) from which are developed ***objectives*** (Clause 5.4.1 requires objectives to be consistent with the quality policy)**.** In planning to meet these objectives the ***processes are identified*** and their ***sequence and interaction*** determined. Once the relationship between processes is known, the ***criteria and methods*** for effective operation and control can be developed and ***documented***. The processes are described in terms that enable their effective communication and a suitable way of doing this would be to compile the process descriptions into a ***quality manual*** that not only references the associated ***procedures*** and ***records*** but also shows how the processes interact. Before implementation the processes need to be ***resourced*** and the ***information*** necessary to operate and control them deployed and brought under ***document control***. Once operational the processes need to be ***monitored*** to ensure they are functioning as planned. ***Measurements*** taken to verify that the processes are delivering the required output and actions taken to ***achieve the planned results***. The data obtained from monitoring and measurement that is captured on ***controlled records*** needs to be ***analysed*** and opportunities for ***continual improvemen***t identified and the agreed actions ***implemented.*** Here we have the elements of the process development process that would normally be part of mission management but that process is largely addressed in the standard through Management Responsibility.

If every quality management system reflected the above linkages the organization's products and services would consistently satisfy customer requirements.

Management responsibility

While the implementation of *all* requirements in ISO 9001 is strictly management's responsibility, those in Section 5 of the standard are indeed the responsibility

Management responsibility

5.1 Management commitment
5.2 Customer focus
5.3 Quality policy
5.4 Planning
5.4.1 Quality objectives
5.4.2 Quality management system planning
5.5 Responsibility, authority and communication
5.5.1 Responsibility and authority
5.5.2 Management representative
5.5.3 Internal communication
5.6 Management review
5.6.1 General
5.6.2 Review input
5.6.3 Review output

of top management. All clauses in this section commence with the phrase "Top management shall. . ." The first four clauses clearly apply to the strategic planning processes of the organization rather than to specific products. However, it is the board of directors that should take note of these requirements when establishing their vision, values, mission and objectives. These requirements are amongst the most important in the standard. There is a clear linkage between customer's needs, policy, objectives and processes. One leads to the other in a continuous cycle. Although the clauses in Section 5 are not intended as a sequence, each represents a part of a process that establishes direction and keeps the organization on course. If we link the requirements together in a cycle (indicating the headings from ISO 9001 in bold italic type) the cycle commences with a ***Vision*** – a statement of what we want to be or do, and then a ***Focus on customers*** for it is the customer that will decide whether or not the organization survives. It is only when you know what your market is, who your customers will be and where they will be that you can define the ***Purpose*** or ***Mission*** of the organization. From the purpose or mission you can devise the ***Policies or Values*** that will guide you on your journey. These policies help frame the ***Objectives,*** the milestones en route towards your destination. The policies won't work unless there is ***Commitment*** so that everyone pulls in the same direction. ***Plans*** have to be made to achieve the objectives and these plans need to identify and layout the ***Processes*** that will be employed to deliver the results – for all work is a process and without work nothing will be achieved. The plans also need to identify the ***Responsibilities and Authority*** of those who will be engaged in the endeavour. As a consequence it is essential that effective channels of ***Internal Communication*** be established to ensure that everyone understands what they are required to achieve and how they are performing. No journey should be undertaken without a means of knowing where you are, how far you have to go, what obstacles are likely to lie in the path ahead or what forces will influence your success. It is therefore necessary to collate the facts on current performance and predictions of what lies ahead so that a ***Management Review*** can take place to determine what action is required to keep the organization on course or whether any changes are necessary to the course or the capability of the organization for it to fulfil its purpose and mission – and so we come full circle. What the requirements of Section 5 therefore address is

the mission management process with the exception of process development, which happens to be addressed in Section 4 of the standard.

Resource management

Section 6 of ISO 9001 draws together all the resources-related requirements that were somewhat scattered in previous versions. Resource management is a key business process in all organizations. In practice, resource management is a collection of related processes that are often departmentally oriented.

Resource management

6.1	Provision of resources
6.2	Human resources
6.2.1	General
6.2.2	Training, awareness and competency
6.3	Infrastructure
6.4	Work environment

- Financial resources are controlled by the Finance Department.
- Purchased materials, equipment and supplies are controlled by the Purchasing Department.
- Measuring equipment maintenance is controlled by the Calibration Department.
- Plant maintenance is controlled by the Maintenance Department.
- Staff development is controlled by the Human Resources Department.
- Building maintenance is controlled by the Facilities Management Department.

These departments control the resources in as much that they might plan, acquire, maintain and dispose of them but do not manage them totally because they are not the sole users or customers of the resource. They therefore only perform a few of the tasks necessary to manage resources. Collectively they control the human, physical and financial resources of the organization.

Whatever the resource, firstly it has to be planned, then acquired, deployed, maintained and eventually disposed of. The detail of each process will differ depending on the type of resource being managed. Human resources are not "disposed off" but their employment or contract terminated. Although ISO 9001 does not address disposal of any resources because it only focuses on intended product, resource disposal impacts the environment and other stakeholders and if an automotive company discharges waste into the ground water, it could lead to prosecutions that displease their customer.

The standard does not address financial resources specifically but clearly they are required to implement and maintain the management system and hence run the organization. Purchasing is not addressed under resource management but under product realization. However, the location of Clauses should not be a barrier to the imagination because their location is not governed by the process approach but by user expectations. Regretably, we cannot link the clauses of this section of the standard into a cycle as we have with the other sections.

Product realization

7.1 Planning of realization processes
7.2 Customer-related processes
7.2.1 Determination of requirements related to the product
7.2.2 Review of requirements related to the product
7.2.3 Customer communication
7.3 Design and/or development
7.3.1 Design and/or development planning
7.3.2 Design and/or development inputs
7.3.3 Design and/or development outputs
7.3.4 Design and/or development review
7.3.5 Design and/or development verification
7.3.6 Design and/or development validation
7.3.7 Control of design and/or development changes
7.4 Purchasing
7.4.1 Purchasing control
7.4.2 Purchasing information
7.4.3 Verification of purchased product
7.5 Production and service provision
7.5.1 Control of production and service provision
7.5.2 Validation of processes
7.5.3 Identification and traceability
7.5.4 Customer property
7.5.5 Preservation of product
7.6 Control of measuring and monitoring devices

Product realization

Product Realization as expressed in Section 7 of ISO 9001 is the Demand Fulfilment Process (see Chapter 6) that has interfaces with Resource Management and Demand Creation processes. It is also the Order to Cash process implying that the inputs are orders and the output is cash, therefore it would include the invoicing and banking activities. However the Product Realization requirements include requirements for purchasing, a process that could fit as comfortably under resource management because it is not limited to the acquisition of components but is a process that is used for acquiring all physical resources including services. Section 7 also includes requirements for control of measuring devices which would fit more comfortably into Section 8 but it omits the control of nonconforming product which is more to do with handling product than measurement. Product realization does not address demand creation or marketing. The demand has already been created when the customer approaches the organization with either an order or invitation to tender. Note that Demand Creation is addressed by the standard only through Clause 5.2 and that product design is located in Section 7 simply because it refers to the design of customer specific products. If the products were designed in order to create a demand this work process would be part of Demand Creation.

If we link the requirements together in a cycle (indicating the headings from ISO 9001 in bold type), having marketed the organization's capability and attracted a customer, the cycle commences by the need to ***communicate with customers*** and ***determine the requirements*** of customers, of regulators and of the organization relative to the product or service to be supplied. This will undoubtedly involve more ***customer communication*** and once requirements have been determined we need to ***review the requirements*** to ensure they are

understood and confirm we have the capability to achieve them. If we have identified a need for new products and services, we would then need to ***plan product realization*** and in doing so use ***preventive action*** methods to ensure the success of the project and take care of any ***customer property*** on loan to us. We would undertake product ***design and development*** and in doing so we would probably need to ***identify product***, ***purchase*** materials, components and services, build prototypes using the process of ***production provision*** and ***validate*** new ***processes.*** After ***design validation*** we would release product information into the market to attract customers and undertake more ***customer-communication***. As customers enquire about our offerings we would once more ***determine the requirements*** in order to match customer needs with product offerings and our ability to supply.

Now faced with real customers demanding our products, we would ***review the requirements*** and confirm we had the capability to supply the product in the quantities and to the delivery schedule required before entering into a commitment to supply. We would then proceed to ***plan product realization*** once again and undertake ***production or service provision.*** During production or service delivery we would maintain ***traceability*** of the product if applicable, perform ***measurement and monitoring*** and ***control the measuring and monitoring devices***. We would ***monitor and measure processes*** and ***monitor and measure products*** at each stage of the process. If we found unacceptable variations in the product we would undertake the ***control of nonconforming product*** and ***analyse data*** to facilitate ***corrective action***. Throughout production or service delivery we would seek the ***preservation of product*** and take care of ***customer property***. Once we had undertaken all the ***product verification*** and ***preserved*** the product for delivery, we would ship the product to the customer or complete the service transaction. To complete the cycle ***customer communication*** would be initiated once more to obtain feedback on our performance.

Here we have linked together all the Clauses in Section 7 and many in Section 8 of the standard because the two cannot be separated.

Measurement, analysis and improvement

Measurement, analysis and improvement processes are vital to the achievement of quality. Until we measure using devices of known integrity, we know little about a process or its outcomes. But if we measure using instruments that are unfit for purpose, we will be misled by the results. With the results of valid measurement we can make a judgement on the basis of facts. The facts will tell us whether we have met the target. Analysis of the facts will tell us whether the target can be met using the same methods or better methods or whether the target is the right target to aim for. Measurements without a target value to compare results of measurement are measurements without a purpose. The target value is therefore vital

Measurement, analysis and improvement

8.1 Planning
8.2 Measurement and monitoring
8.2.1 Customer satisfaction
8.2.2 Internal audit
8.2.3 Measurement and monitoring of processes
8.2.4 Measurement and monitoring of product
8.3 Control of nonconformity
8.4 Analysis of data
8.5 Improvement
8.5.1 Planning for continual improvement
8.5.2 Corrective action
8.5.3 Preventive action

but arbitrary values demotivate personnel. Targets should always be focused on purpose so that through the chain of measures from corporate objectives to component dimensions there is a soundly based relationship between targets, measures, objectives and the purpose of the organization, process or product.

Measurement tells us whether there has been a change in performance. Change is a constant. It exists in everything and is caused by physical, social or economic forces. When we measure the same parameter on different items we expect slight variation. However, if we measure the same parameter using the same device we might not expect there to be a change, but the inaccuracies inherent in the measuring system will lead to a variation in readings. To understand change we need to understand its cause. Some change is represented by variation about a norm and is predictable – it is a natural phenomenon of a process and when it is within acceptable limits it is tolerable. Other change is represented by erratic behaviour and is not predictable but its cause can be determined and eliminated through measurement, analysis and improvement.

Measurement, analysis and improvement are strictly sub-processes within each business process. However parent processes will often capture data from monitoring and measurements within sub-processes. This may happen when assessing a variety of data from individual processes to determine customer satisfaction or for discovering common cause problems and subsequently devising company wide improvement programmes.

There is a sort of logic in the structure of the requirements in this section but there are some gaps. It would have assisted understanding if the same terms as used in Clause 8.1 had been used in the headings of Clauses 8.2 to 8.5. In that way the relationships would have been more obvious. The general requirements of Clause 8.1 are amplified by Clauses 8.2 to 8.5 so the requirements in Clause 8.1 are not separate to those in Clauses 8.2 to 8.5 with the exception of Clause 8.3 on the control of nonconforming product and those on statistical techniques. This later requirement is stated once because it applies to all monitoring, measurement and analysis processes. Clause 8.3 on nonconforming product appears in Section 8 not because it has anything to do with measurement, analysis and improvement but because its inclusion in Section 7 would imply that it could be excluded from the management system (see ISO 9001 Clause 1.2).

It should not be assumed that Section 8 includes all requirements on measurement, analysis and improvement.

Measurement and monitoring is also addressed by:

- Management representative (5.5.2) – in the context of reporting on system performance.
- Management review (5.6) – in the context of reviewing system adequacy.
- Control of monitoring and measurement devices (7.6).
- Design and development verification (7.3.5).
- Design and development validation (7.3.6).
- Verification of purchased product (7.4.3).

Analysis is also addressed by:

- Management review (5.6) – in the context of changes that could affect the management system.
- Control of design and development changes (7.3.7) – in the context of evaluation of the effects of change.
- Control of monitoring and measuring devices (7.6) – in the context of measurement systems.

Improvement is also addressed by:

- Management review (5.6) – in the context of changes to quality policy.
- Control of design and development changes (7.3.7).
- Internal communication (5.5.3) – in the context of communicating the effectiveness of the management system.
- Provision of resources (6.1) in the context of resources needed for continual improvement.

We can link the requirements of Section 8 together in a number of separate cycles (indicating the headings from ISO 9001 in bold italic type).

During the design and development of the business and work processes we would undertake a review of the established practices to identify potential problems and undertake ***preventive action*** to prevent occurrence of such problems. Before implementing the management system processes or any changes thereto, we would perform ***internal audits*** (or undertake ***process validation***) to determine whether these processes met the relevant requirements of the standard, enabled the organization to fulfil its ***policies*** and ***objectives*** and produce the required products and services. Any potential problems discovered would be subject to ***preventive action*** to prevent occurrence of such problems. At appropriate stages in the production process we would ***monitor and measure product*** for compliance with specified requirements, periodically undertake *product audits* to establish the effectiveness of the process controls, initiate ***control of nonconforming product*** on detecting nonconformity and undertake ***corrective action***

when process targets had not been met. After introducing new or changed practices and periodically thereafter, we would perform ***internal audits*** to determine whether the planned arrangements were being implemented as intended and undertake ***corrective action*** to bring about ***improvement*** by better control. Periodically we would ***monitor and measure processes*** for their ability to achieve planned results and undertake *process audits* to establish whether the achieved results arose from implementing the planned arrangements and if necessary, undertake corrective action to reduce variation and bring about ***improvement*** by better control. We would also ***analyse data*** resulting from these reviews and bring about ***improvements*** by better utilization of resources. Some time after establishing the ***organization's purpose,*** setting ***policies*** and ***objectives*** that were ***customer focused*** and installed the enabling ***processes*** we would collect and ***analyse data*** in order to monitor ***customer satisfaction*** and undertake ***corrective action*** to bring about ***improvement*** by better control.

One observes from this consolidation that the order in which the Clauses are mentioned is not remotely the same as the order they are addressed in the standard, that some Clauses in the standard appear several times and others are drawn from other sections thus demonstrating that you cannot treat the Clauses in isolation or in any particular sequence.

Performance improvement

ISO 9001 contains a set of requirements, which if met, will enable organizations to supply products, and services that satisfy customer requirements. Depending on how these requirements are interpreted it may enable organizations to go much further but organizations are not compelled to do so to gain certification. ISO 9004 covers a wider range of objectives than ISO 9001 and addresses the continual improvement of an organization's overall performance and therefore goes beyond customers and addresses the needs and expectations of all stakeholders.

The strategy underpinning this consistent pair of standards is that you can develop your management system so that it meets ISO 9001 and hence give you the capability of satisfying customer requirements, and subsequently implement the recommendations of ISO 9004 to extend the scope of your management system so that it enables you to satisfy all stakeholders.

You could of course start with ISO 9004 and then simply apply for ISO 9001 certification. The self assessment questionnaire in ISO 9004 is useful but the assessment criteria for the Excellence Model is far better and wider ranging.

Summary

In this Chapter we have examined the roots of ISO 9000 and shown that the principles on which it is based were born many centuries ago. We have shown

how ISO 9000 certification came out of a quest for confidence by customers and how organizations were motivated to establish management systems as a way of increasing their capability so as to create and retail satisfied customers. We have examined the relationship between the standards in the ISO 9000 family and shown how each of the primary requirements in ISO 9001 are linked together to form a coherent set of elements. After analysing each section of ISO 9001 requirements in plane English a picture emerges that enables us to see how we can manage the achievement of quality using ISO 9000. Going further to embrace the recommendations of ISO 9004 will get you closer to the Excellence Model.

ISO 9000 is a useful family of standards and has had more success that any other initiative primarily because ISO 9001 certification has been used as a pre-requisite for trade. As a result neither of the other standards in the family (ISO 9000 and ISO 9004) have penetrated as deep as ISO 9001 so the concepts and principles upon which ISO 9000 is based are not widely understood. There has been a rather narrow interpretation of the requirements which regrettably has prevented ISO 9000 from becoming a model of excellence that Chief Executive Officers would use in the running of their business.

The many misconceptions that have surrounded the standard are addressed in the next chapter.